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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,227	DOTAN ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-30 and 43-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-30 and 43-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 January 2008 has been entered.

Claims 43-63 are newly added. Claims 7 and 31-42 have been cancelled. Claims 1-6, 8-30, and 43-63 remain in the case.

The disclosure is objected to because of the following informalities: the column headings on Tables 2 and 3 are not legible. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-6, 8-21, and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant teaches elevation of antibodies specific for various oligosaccharide structures in patients with inflammatory bowel disease, particularly Crohn's disease. However, detection of elevated levels of anti- GlcNAc (β 1-4) GlcNAc(β) antibodies is specifically taught as indicative of antiphospholipid syndrome (see e.g.: pages 6-7 and 19-20; Fig. 2a). Crohn's disease shares some symptoms with antiphospholipid syndrome, such as anemia. Thus, absent further guidance from applicant, one would not be assured of the ability to successfully practice the invention as instantly claimed because one could not diagnose a patient as having Crohn's disease performing the method as claimed. Moreover, although the headings of Tables 2 and 3 are not clear, it would seem that one could not be assured of the ability to successfully practice the invention of the scope as instantly claimed in the absence of specifically detecting IgA anti-GlcNAc (β 1-4) GlcNAc(β) antibodies in a subject suspected of having Crohn's disease. Further, with regard to claims merely identifying other antibodies in samples, as set forth for the reasons of record in the prior rejection of the similar subject matter of the invention as previously claimed, and in the absence of further guidance from applicant, one would not be assured of the ability to successfully practice the invention as instantly claimed because one would doubt, on its face, that a diagnosis could be made based upon determining merely the presence of at least one, or several, of the antibodies.

Applicant's arguments filed 11 January 2008 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-29, 30, and 43-63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, the metes and bounds of the invention for which applicant desires coverage is not clear because it is not clear which or how many symptoms are intended in order to define the subject population. Thus the claims fail to particularly point out and distinctly claim the intended subject matter.

In claim 5 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. Further, in claim 15 and claims dependent thereupon, it is not clear which of the antibodies identified is "said" antibody.

In claim 6, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 8 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim are not clear, e.g. it is not clear if diagnosis requires either or both of the antibodies. Further, in claim 10 it is not clear what diagnosis is to be made if all three of the antibodies are determined as elevated/present. The examiner would suggest that language similar to that of claim 29, --subject is further assessed as having . . . ANCA are absent . . . --, may be clearer.

In claim 9, the interrelationships of the steps to those of the independent claim are not clear, e.g. it is not clear what diagnosis is to be made if both of the antibodies are determined as elevated/present. The examiner would suggest that language similar to that of claim 29, --subject is further assessed as having . . . ANCA are absent . . . --, may be clearer.

In claim 11, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

Claim 19 adds additional anti-glycan antibodies (e.g., anti-GlcNAc(β)6-sulfate, anti-xylan, etc.) and, thus, does not properly limit the previously recited subject matter.

In claim 22 and claims dependent thereupon, the metes and bounds of the invention for which applicant desires coverage is not clear because it is not clear which or how many symptoms are intended in order to define the subject population. Thus the claims fail to particularly point out and distinctly claim the intended subject matter.

In claim 24, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 25, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 26 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim are not clear, e.g. it is not clear if diagnosis requires either or both of the anti-glycan and anti-mannan antibodies.

In claim 46 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. Further, in claim 54

and claims dependent thereupon, it is not clear which of the antibodies identified is "said" antibody.

In claim 47, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 48 and claims dependent thereupon, the interrelationships of the steps to those of the independent claim are not clear, e.g. it is not clear if diagnosis requires either or both of the antibodies. Further, in claim 50 it is not clear what diagnosis is to be made if all three of the antibodies are determined as elevated/present. The examiner would suggest that language similar to that of claim 29, --subject is further assessed as having . . . ANCA are absent . . . --, may be clearer.

In claim 49, the interrelationships of the steps to those of the independent claim are not clear, e.g. it is not clear what diagnosis is to be made if both of the antibodies are determined as elevated/present. The examiner would suggest that language similar to that of claim 29, --subject is further assessed as having . . . ANCA are absent . . . --, may be clearer.

Claim 58 adds additional anti-glycan antibodies (e.g., anti-GlcNAc(β)6-sulfate, anti-xylan, etc.) and, thus, does not properly limit the previously recited subject matter.

In claim 61, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear.

In claim 30, the metes and bounds of the invention for which applicant desires coverage is not clear because it is not clear which or how many symptoms are intended in order to define the subject population. Thus the claims fail to particularly point out and distinctly claim the

intended subject matter. Moreover, the test sample should be provided from "the" subject to provide a proper interrelationship between the subject, sample, and diagnosis.

Applicant's arguments filed 11 January 2008 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-28, 43-45, 48, 51-53, and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by Main et al. (BMJ 297: 1105, 1988) in light of the instant disclosure, Sendid et al. (Clin. Diagn. Lab. Immunol. 3: 219, 1996), and/or Wakshull et al. (US 6,294,321) for reasons of record.

Claims 22-28, 43-45, 48, 51-53, and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sendid et al. (Clin. Diagn. Lab. Immunol. 3: 219, 1996) in light of the instant disclosure and/or Wakshull et al. (US 6,294,321) for reasons of record.

Claim 30 is rejected under 35 U.S.C. § 102(b) as being anticipated by Quinton et al. (Gut 42: 788, 1998) in light of Walsh et al. (US 6,218,129) for reasons of record.

Applicant's arguments, and the declaration of Dr. Nir Dotan under 37 CFR 1.132, filed 11 January 2008 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the references did not identify specific anti-glycan antibodies as now claimed. This is not found persuasive for the reasons of record that the assays of the references inherently detected antibodies to the glycan epitopes, e.g. β (1-3)-glucans and mannans, present in the yeast cells.

Applicant, in the declaration and arguments thereto, urges that the instant application was filed based on using defined glycans for screening of serum samples. This is not found persuasive because the argument is not commensurate in scope with the invention as claimed because the invention as claimed does not require the immobilized defined glycans as argued. Notwithstanding applicant's assertion to the contrary, the rejections of record rely upon the detection of antibodies to the particular strains in the references shown as having relevant epitopes and the rejections are not directed to the detection of antibodies to *Saccharomyces cerevisiae*, generally. Moreover, and notwithstanding applicant's arguments to the contrary, the issue is also not statistical correlation of the antibody responses to polysaccharide and to defined subfragments thereof, or whether antibodies directed to a polysaccharide bind to a defined subfragment, or what organism elicited the antibodies, the issue is if antibodies which bind to a defined subfragment and which bind to that epitope in a polysaccharide comprising the epitope in a population of polysaccharides are detectable in the methods of the references using whole yeast cell preparations, which include β (1-3)-glucans and mannans, and not merely a mannan-containing portion of the polysaccharides derived from the whole yeast cells. Applicant's arguments present nothing which challenges the inherency of the methods, as set forth, to detect the relevant binding.

Applicant urges that the reference of Wakshull et al. does not discuss Crohn's disease. This is not found persuasive for the reasons of record that the reference is cited merely to provide evidence of the inherency of the presence of β (1-3)-glucans in yeast cells.

Applicant urges that the reference of Quinton et al. did not detect specific anti-glycan antibodies. This is not found persuasive because the detection of anti-glycan antibodies is recited in the alternative and is not required by the rejected claim.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-30, and 43-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, 11-29, and 73-91 of copending Application No. 10/843,033 for reasons of record.

Claims 1-6, 8-30, and 43-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29, 55-57, and 59 of copending Application No. 11/351,185 for reasons of record.

Claims 1-6, 8-30, and 43-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7, 8, 11, 18-22, 28, 30-32, 36, 37, 40, 47-51, 54-65, and 70-73 of copending Application No. 11/364,964 for reasons of record.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Applicant's arguments filed 11 January 2008 have been fully considered but they are not deemed to be persuasive. Applicant's deferment of addressing the rejection is noted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
March 6, 2008

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641